Claims

- 1. A fluid dispensing device for spraying a fluid into a body cavity comprising a housing, a nozzle for insertion into a body cavity, a fluid discharge device moveably housed within the housing, the fluid discharge device having a longitudinal axis and comprising a container containing a fluid medicament formulation to be dispensed and a compression pump having a suction inlet located within the container and a discharge tube extending along the longitudinal axis for transferring fluid from the pump to the nozzle and finger operable means moveable with respect to the longitudinal axis of the fluid discharge device to apply a force to the container to move the container along the longitudinal axis towards the nozzle so as to actuate the compression pump wherein a pre-load means is provided to prevent actuation of the compression pump until a pre-determined force is applied to the finger operable means, and wherein said fluid medicament formulation has a viscosity of from 10 to 2000 mPa.s at 25°C.
- 15 2. A fluid dispensing device as claimed in claim 1 in which the finger operable means comprises of at least one lever pivotally connected to part of the housing and arranged to act upon the container so as to urge the container towards the nozzle when the or each lever is moved by a user.
- 3. A fluid dispensing device as claimed in claim 2 in which there are two opposing levers, each of which is pivotally connected to part of the housing and is arranged to act upon the container so as to urge the container towards the nozzle when the two levers are squeezed together by a user.
- 4. A fluid dispensing device as claimed in claim 1 in which the finger operable means comprises at least one lever to apply a force to an actuating means used to move the container towards the nozzle so as to actuate the pump.

- 5. A fluid dispensing device as claimed in claim 4 in which the or each lever is pivotally supported at a lower end within the housing and the actuating means is connected to a neck of the container.
- 6. A fluid dispensing device as claimed in claim 5 in which there are two opposing levers, each of which is pivotally supported near a lower end of the housing and is arranged to act upon the actuating means so as to urge the container towards the nozzle when the two levers are squeezed together by a user.
- 7. A fluid dispensing device as claimed in claim 1 in which the finger operable means comprises of at least one lever slidably supported within the housing to apply a force to the container so as to move the container towards the nozzle and actuate the compression pump.
 - 8. A fluid dispensing device as claimed in any of claims 1 to 7 in which the preload means is interposed between the finger operable means and the container.
- 9. A fluid dispensing device as claimed in claim 8 in which the pre-load means 15 comprises of a step formed on the container which must be ridden over by the finger operable means before the compression pump can be actuated wherein the step is over-ridden when the pre-determined force is applied to the finger operable means.
- 10. A fluid dispensing device as claimed in claim 8 in which the pre-load means comprises of a step formed on the finger operable means that must be ridden over by the container before the compression pump can be actuated wherein the step is over-ridden when the pre-determined force is applied to the finger operable means.
- 11. A fluid dispensing device as claimed in claim 8 in which the pre-load means comprises of at least one detent formed on one of the container or the finger operable means and a recess formed on the other of the container or the finger operable means wherein the or each detent is able to ride out of the recess with which it is engaged when the pre-determined force is applied to the finger operable means.

- 12. A fluid dispensing device as claimed in any of claims 1 to 7 in which the preload means is interposed between the housing and the container.
- 13. A fluid dispensing device as claimed in claim 12 in which the pre-load means comprises of one or more detents formed on the container for engagement with part of the housing, the or all of the detents being disengageable from the housing when the pre-determined force is applied to the finger operable means so as to allow the compression pump to be actuated.
- 14. A fluid dispensing device as claimed in claim 12 in which the pre-load means comprises of one or more detents formed on the housing for engagement with part of the container, the or all of the detents being disengageable from the container when the pre-determined force is applied to the finger operable means so as to allow the compression pump to be actuated.
 - 15. A fluid dispensing device as claimed in any of claims 1 to 7 in which the preload means is interposed between the container and the discharge tube.
- 15 16. A fluid dispensing device as claimed in claim 15 in which the pre-load means comprises of a step formed on the discharge tube and at least one latching member attached to the container, the arrangement being such that, when the pre-determined force is applied to the finger operable means, the or each latching member is able to ride over the step so as to allow the compression pump to be actuated.
- 17. A fluid dispensing device as claimed in which the pre-load means comprises of a recess formed on the discharge tube and at least one latching member attached to the container, the arrangement being such that, when the pre-determined force is applied to the finger operable means, the or each latching member is able to ride out of the recess so as to allow the compression pump to be actuated.
 - 18. A fluid dispensing device as claimed in any of claims 1 to 7 in which the preload means is interposed between the housing and the finger operable means.

- 19. A fluid dispensing device as claimed in claim 18 in which the pre-load means comprises of at least one detent formed on the housing for engagement with the finger operable means, the or all of the detents being disengageable from the finger operable means when the pre-determined force is applied to the finger operable means so as to allow the compression pump to be actuated.
- 20. A fluid dispensing device as claimed in claim 18 in which the pre-load means comprises of at least one detent formed on the finger operable means for engagement with part of the housing, the or all of the detents being disengageable from the housing when the pre-determined force is applied to the finger operable means so as to allow the compression pump to be actuated.
 - 21. A fluid dispensing device as claimed in any of claims 4 to 6 in which the preload means is interposed between the actuating means and the housing.
- 22. A fluid dispensing device as claimed in claim 21 in which the pre-load means comprises of at least one detent formed on part of the actuating means for engagement with part of the housing, the or all of the detents being disengageable from the housing when the pre-determined force is applied to the finger operable means so as to allow the compression pump to be actuated.
- 23. A fluid dispensing device as claimed in claim 21 in which the pre-load means comprises of at least one detent formed on part of the housing each detent being arranged for engagement with a complementary recess formed on part of the actuating means, each detent being disengageable from its respective recess when the pre-determined force is applied to the finger operable means so as to allow the compression pump to be actuated.
- 24. A fluid dispensing device as claimed in any of claims 4 to 6 in which the pre-25 load means is interposed between the finger operable means and the respective actuating means.

- 25. A fluid dispensing device as claimed in claim 24 in which the pre-load means comprises of at least one detent formed on each lever for engagement with a respective recess formed on part of the actuating means, each detent being disengageable from its respective complementary recess when the pre-determined force is applied to the lever so as to allow the compression pump to be actuated.
- 26. A fluid dispensing device as claimed in claim 24 in which the pre-load means comprises of at least one detent formed on each actuating means for engagement with a recess formed on a respective finger operable means, each detent being disengageable from its respective complementary recess when the pre-determined force is applied to the finger operable means so as to allow the compression pump to be actuated.
- 27. A fluid dispensing device as claimed in claim 24 in which the pre-load means defines a variable mechanical ratio such that until the pre-determined force is applied to the or each lever no significant force is transferred to the container along the longitudinal axis.
 - 28. A fluid dispensing device, as claimed in claim 27, wherein said variable mechanical ratio is defined by the profile of interaction of a surface of the finger operable means with a follower element provided to the container or a fitting provided thereto.
- 20 29. A fluid dispensing device as claimed in claim 28, wherein said fitting comprises a collar.
 - 30. A fluid dispensing device as claimed in any of claims 27 to 29, wherein the variable mechanical ratio has a two-stage profile comprising an initial high gradient profile and a subsequent lower gradient profile.
- 25 31. A fluid dispensing device as claimed in claim 30, wherein the high and lower gradient profiles are both linear.

WO 2005/044354

- 32. A fluid dispensing device as claimed in claim 30, wherein the high and low gradient profiles are both curved and have a smooth break point therebetween.
- 33. A fluid dispensing device as claimed in claim 32, wherein the high and low gradient profiles both have part-circle forms.
- 5 34. A fluid dispensing device as claimed in any of claims 12 to 17 in which the finger operable means comprises of a single lever and the pre-load means further comprises of a spring interposed between the lever and the container, the spring being used to urge the container towards the nozzle so as to actuate the compression pump.
- 10 35. A fluid dispensing device as claimed in claim 34 in which the spring is compressed by movement of the lever until the pre-determined force is applied, at which point the means used to prevent actuation of the compression pump are overcome by the force being applied to the container by the spring and the container moves rapidly towards the nozzle so as to actuate the compression pump.
- 15 36. A fluid dispensing device as claimed in any of claims 1 to 35 additionally comprising force modifying means for modifying the force applied to the container by the finger operable means.
 - 37. A fluid dispensing device as claimed in claim 36 in which said force modifying means amplifies the force applied to the container by the finger operable means.
- 20 38. A fluid dispensing device as claimed in claim 37 in which the amplification is provided in a uniform manner.
 - 39. A fluid dispensing device as claimed in claim 38 in which the degree of amplification is from 1.5 to 10.
- 40. A fluid dispensing device as claimed in any of claims 36 to 39 in which the force modifying means is integral with the finger operable means.

- 41. A fluid dispensing device as claimed in any of claims 36 to 39 in which the force modifying means is located between the finger operable means and the container.
- 42. A fluid dispensing device as claimed in any of claims 36 to 41 in which the 5 force modifying means comprises a lever, cam or screw element.
 - 43. A fluid dispensing device as claimed in any of claims 36 to 42 in which the force modifying means acts once the pre-determined force has been applied to the finger operable means.
- 44. A fluid dispensing device as claimed in claim 43 in which the force modifying means acts such that once the pre-determined force has been applied to the finger operable means the modified force applied to the container is relatively constant.
- 45. A fluid dispensing device as claimed in claim 43 in which the force modifying means acts such that once the pre-determined force has been applied to the finger operable means the modified force applied to the container increases on a relatively constant basis.
 - 46. A fluid dispensing device as claimed in any of claims 36 to 45 in which the force modifying means additionally comprises a stop element.
- 47. A fluid dispensing device as claimed in any of claims 1 to 46 wherein said fluid medicament formulation has a viscosity of from 20 to 1000 mPa.s, preferably 20 from 50 to 1000 mPa.s at 25°C.
 - 48. A fluid dispensing device as claimed in claim 47, wherein said fluid medicament formulation is in the form of a solution formulation.
- 49. A fluid dispensing device as claimed in claim 47, wherein said fluid medicament formulation is in the form of a suspension formulation comprising a suspension of active medicament particles in an inert suspending formulation.

- 50. A fluid dispensing device as claimed in any of claims 47 to 49, wherein the fluid medicament formulation comprises an anti-inflammatory medicament compound.
- 51. A fluid dispensing device as claimed in claim 50, wherein said medicament 5 compound is a glucocorticoid compound.
- 52. A fluid dispensing device as claimed in claim 51, wherein said glucocorticoid compound is selected from the group consisting of 6α , 9α -Difluoro- 17α -(1-oxopropoxy)- 11β -hydroxy- 16α -methyl-3-oxo-androsta-1,4-diene- 17β -carbothioic acid S-fluoromethyl ester; 6α , 9α -difluoro- 17α -[(2-furanylcarbonyl)oxy]- 11β -hydroxy- 16α -methyl-3-oxo-androsta-1,4-diene- 17β -carbothioic acid S-fluoromethyl ester; and $6\alpha,9\alpha$ -Difluoro- 11β -hydroxy- 16α -methyl- 17α -[(4-methyl-1,3-thiazole-5-carbonyl)oxy]-3-oxo-androsta-1,4-diene- 17β -carbothioic acid S-fluoromethyl ester.
- 53. A fluid dispensing device as claimed in claim 50, wherein said medicament compound is selected from the group consisting of PDE4 inhibitors, leukotriene antagonists, iNOS inhibitors, tryptase and elastase inhibitors, beta-2 integrin antagonists and adenosine 2a agonists.

54. Kit of parts comprising

(a) a housing assembly for reversible receipt of a fluid discharge device for spraying a fluid into a body cavity, said fluid discharge device having a longitudinal axis and comprising a container for containing a medicament suspension formulation to be dispensed and a compression pump having a suction inlet located within the container and a discharge tube extending along the longitudinal axis for transferring fluid from the pump to the nozzle, the housing assembly comprising a housing, a nozzle for insertion into a body cavity and finger operable means moveable with respect to the longitudinal axis of the fluid discharge device to apply a force to the container to move the container along the longitudinal axis towards the nozzle so as to actuate the compression pump wherein a pre-load means is provided to prevent

WO 2005/044354 PCT/GB2004/004626

87

actuation of the compression pump until a pre-determined force is applied to the finger operable means; and

- (b) a fluid discharge device having a longitudinal axis and comprising a container containing a fluid medicament formulation to be dispensed and a compression pump having a suction inlet located within the container and a discharge tube extending along the longitudinal axis for transferring fluid from the pump to the nozzle, wherein said fluid medicament formulation has a viscosity of from 10 to 2000 mPa.s.
 - 55. A fluid dispensing device for spraying a fluid into a body cavity substantially as described herein with reference to the accompanying drawings.